



Food and Drug Administration
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October 30, 2014

SIEMENS HEALTHCARE DIAGNOSTICS, INC.
DONNA VELASQUEZ
REGULATORY TECHNICAL SPECIALIST
5210 PACIFIC CONCOURSE DRIVE
LOS ANGELES CA 90045

Re: K142878

Trade/Device Name: IMMULITE® 2000 Beta-2 Microglobulin Calibration Verification
Material and IMMULITE® 2000 High Sensitivity CRP Calibration
Verification Material

Regulation Number: 21 CFR 862.1660

Regulation Name: Quality control material (assayed and unassayed)

Regulatory Class: I, Reserved

Product Code: JJX

Dated: September 30, 2014

Received: October 02, 2014

Dear Ms. Donna Velasquez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

k142878

Device Name

IMMULITE® 2000 Beta-2 Microglobulin Calibration Verification Material

Indications for Use (Describe)

IMMULITE® 2000 Beta-2 Microglobulin Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Beta-2 Microglobulin assay on the IMMULITE 2000 systems

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Indications for Use

510(k) Number (if known)
k142878

Device Name
IMMULITE® 2000 High Sensitivity CRP Calibration Verification Material

Indications for Use (Describe)

IMMULITE® 2000 High Sensitivity CRP Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE High Sensitivity CRP assay on the IMMULITE 2000 systems

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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PRASStaff@fda.hhs.gov

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510(k) Summary

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient details to understand the basis for determination of substantial equivalence.

The assigned 510(k) Number: _____

1. Submitter

Mailing Address:

Siemens Healthcare Diagnostics Inc.
5210 Pacific Concourse Drive
Los Angeles, CA 90045

Contact Person:

Donna Velasquez
Regulatory Technical Specialist

Phone Number:

(310)-645-8200 x7403

Fax Number:

(310)-645-9999

E-mail Address:

donna.velasquez@siemens.com

Date Prepared:

October 28th, 2014

2. Device Name

Proprietary Name:

IMMULITE® 2000 Beta-2 Microglobulin Calibration Verification Material

Measurand:

Quality Control materials for IMMULITE® 2000 Beta-2 Microglobulin assay

Type of Test:

Calibration Verification Material (CVM) for IMMULITE® 2000 Beta-2 Microglobulin assay

Regulation Section:

21 CFR 862.1660, Quality Control Material

Classification:

Class I Reserved

Products Code:

JJX – Single (Specified) Analyte Controls (Assayed and Unassayed)

Panel:

Clinical Chemistry (75)

3. Predicate Device Name

IMMULITE® 2000 Intact PTH Calibration Verification Material (CVM)

Predicate 510(k) No:

K140258

4. Device Description:

The IMMULITE® 2000 Beta-2 Microglobulin Calibration Verification Material (CVM) contains one set of four vials each 3mL. CVM1 contains bovine protein buffer matrix with preservatives and CVM2, CVM3, and CVM4 contain various levels of human Beta-2 Microglobulin in a lyophilized bovine protein buffer matrix with preservatives.

5. Intended Use:

Indication for Use:

See Indications for Use Statement below

The IMMULITE® 2000 Beta-2 Microglobulin Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Beta-2 Microglobulin assay on the IMMULITE 2000 systems

Special Conditions for Use Statement(s):

For prescription use only

Special Instrument Requirements:

IMMULITE® 2000 Systems

6. Technological Characteristics and Substantial Equivalence Comparison with Predicate:

A comparison of the device features, intended use, and other information demonstrates that the IMMULITE® 2000 Beta-2 Microglobulin Calibration Verification Material (CVM) is substantially equivalent to the predicate device as summarized in **Table 1**.

Table 1: Substantial Equivalence Comparison

SIMILARITIES		
	Candidate Device IMMULITE 2000 Beta-2 Microglobulin CVM	Predicate Device IMMULITE 2000 Intact PTH CVM
Intended Use	The IMMULITE® 2000 Beta-2 Microglobulin Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Beta-2 Microglobulin assay on the IMMULITE 2000 systems.	The IMMULITE® 2000 Intact PTH Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Intact PTH assay on the IMMULITE 2000 systems
Storage	≤20°C	Same
Form	Lyophilized	Same
Stability	Stable unopened until the expiration date	Same
Levels	4	Same
Matrix	Buffered bovine/protein with preservatives	Same
Use	Single Use Only	Same
DIFFERENCES		
	Candidate Device IMMULITE 2000 Beta-2 Microglobulin CVM	Predicate Device IMMULITE 2000 Intact PTH CVM
Analyte	Beta-2 Microglobulin	Intact PTH

7. Non-Clinical Performance Testing

Performance testing has been carried out to demonstrate that this device meets the performance specifications for its intend use. The following tests were performed on the candidate device.

Stability Summary:

The stability study was conducted to validate real-time shelf life and open component (in-use or open vial) claim for the IMMULITE 2000 Beta-2 Microglobulin Calibration Verification Material (CVM) to ensure that it maintains optimal product performance on IMMULITE 2000 platforms throughout the established shelf life of the CVM. The Calibration Verification Materials are stable up to 9 years when

stored at -20°C prior to opening. Real time stability testing will continue for lots 011 and 012 until 119 month time point.

Open Component stability studies presents results that support 8 hours of stability at ambient or room temperature (15-25°C) after opening.

Stability Protocol Summary:

The CVM study protocols are run as part of the calibrator stability testing. The stability calibrators/CVMs are run in duplicate (as a minimum) at the time points shown in **Table 2a-c**, and the dose value is determined from the reference calibrator curve.

Table 2a: Stability Protocol Summary - LBMCVM Lot 010

CVM Level	Time-Points (Months)			
LBMCVM1	Day 0	92	110	119
LBMCVM2	Day 0	92	110	119
LBMCVM3	Day 0	92	110	119
LBMCVM4	Day 0	92	110	119

Table 2b: Stability Protocol Summary - LBMCVM Lot 011

CVM Level	Time-Points (Months)			
LBMCVM1	Day 0	36	48	72
LBMCVM2	Day 0	36	48	72
LBMCVM3	Day 0	36	48	72
LBMCVM4	Day 0	36	48	72

Table 2c: Stability Protocol Summary - LBMCVM Lot 012

CVM Level	Time-Points (Months)			
LBMCVM1	Day 0	18	36	42
LBMCVM2	Day 0	18	36	42
LBMCVM3	Day 0	18	36	42
LBMCVM4	Day 0	18	36	42

For Open Component testing, the results were determined from a 2-point adjustment. Using IMMULITE 2000 Beta-2 Microglobulin (L2KBM) kit lot 247, CVM lot 012 was tested at 2-hourly intervals for up to 9 hours at ambient or room temperature (15-25°C) conditions.

Stability Acceptance Criteria Summary:

The Acceptance Criteria for the Beta-2 Microglobulin Calibration Verification Material (CVM) are in 2 parts. Part 1 consists of guideline acceptance criteria which require dose value of stability calibrators/CVM to fall between $\pm 15\%$ of assigned dose for CVM level 2 and $\pm 20\%$ for levels 3 and 4. Part 2 review limits criteria which require dose value of the controls to be within 2 Standard Deviations (SD) of the control target value when generated from the stability calibrator curve. If the result is not within acceptable dose range of $\pm 15\%$ of assigned dose for CVM level 2 and $\pm 20\%$ for levels 3 and 4, then additional data review is conducted using part 2 criteria.

Traceability:

The IMMULITE 2000 Beta-2 Microglobulin CVMs are traceable to an internal material which has been gravimetrically prepared. The CVMs are manufactured using qualified materials and measurement procedures.

Value Assignment:

The IMMULITE 2000 Beta-2 Microglobulin CVMs are 4 level materials which are a subset of 7 level Beta-2 Microglobulin calibrators. Calibrators are not commercialized but are used internally during manufacture and release testing of Beta-2 Microglobulin reagents and two point adjustors. The IMMULITE calibrators and therefore CVMs are value assigned using assigned reference calibrators. The CVMs are manufactured using qualified materials and measurement procedures. The CVMs dose values are generated using curve generated by assigned reference calibrators. The CVM values are calculated based on the recovered values for each run on each instrument independently. CVM values are then averaged across all systems. Quality control is performed by calculating the recovery of patient samples, spiked patient samples and controls using the assigned CVM values. Three levels of commercially available controls and 40 patient samples (20 spiked and diluted urine samples, 10 neat urine samples and 10 diluted serum samples) were used to validate calibrator/CVM value assignments.

Expected Values/Target Values/Reference Range:

Each CVM level was tested for a total of 15 replicates; 5 runs and 3 replicates per run, 3 different reagent kit lots and 5 IMMULITE 2000 systems. The Guideline Range (95% confidence interval) for each CVM level was established based on the Target Mean and ± 2 Standard Deviation (SD). The target values are provided in the IMMULITE[®] 2000 CVM Calibration verification Material lot-specific value card. The expected assay range is 4 to 500 ng/mL. The target values in **Table 3** can be considered as guidelines.

Table 3: Analyte Target Range Values

Analyte target levels	CVM Level	*Target Mean (ng/mL)	Standard Deviation (SD)	Guideline ± 2 SD Range (ng/mL)	
	LBMCMV1	0.00	-	0.00	≤ 4.0
	LBMCMV2	27.8	2.8	22.2	33.4
	LBMCMV3	225	23.5	178	272
	LBMCMV4	504	50.5	403	605
Assay Range	4 to 500 ng/mL				

Note * When CVMs are run by the customer, an actual value below and above the assay range will result when the customer programs the CVMs as calibration verifiers in the instrument software. If programmed as a patient or control, then the software will give values as $<$ or $>$ the assay lower and upper range.

Each laboratory should establish their limits for acceptability based on methodology, clinical significance and medical decision levels of the test analyte. The representative, total precision tabulated in the respective assay instructions for use may be considered as one factor when establishing local, acceptable ranges. The values provided above may be considered as guidelines. Value assignment is lot specific.

Standard/Guidance Documents Referenced:

- CEN 13640 Stability Testing of In Vitro Diagnostic Reagents
- Guidance for Industry – Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators
- Guidance for Industry and FDA Staff – Assayed and Unassayed Quality Control Material

Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10

8. Conclusion:

The IMMULITE® 2000 Beta-2 Microglobulin Calibration Verification Material is substantially equivalent to the predicate device intended for similar use. The substantial equivalence of the device is supported by the non-clinical testing and was found to be comparable and supports the claims of substantial equivalence, product safety and effectiveness. Based on the testing completed and the comparisons with predicate device, the IMMULITE® 2000 Beta-2 Microglobulin Calibration Verification Material does not raise any new questions on safety and effectiveness and the results support a determination of substantial equivalence.

510(k) Summary

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient details to understand the basis for determination of substantial equivalence.

The assigned 510(k) Number: _____

1. Submitter

Mailing Address:

Siemens Healthcare Diagnostics Inc.
5210 Pacific Concourse Drive
Los Angeles, CA 90045

Contact Person:

Donna Velasquez
Regulatory Technical Specialist

Phone Number:

(310) 645-8200 x7403

Fax Number:

(310) 645-9999

E-mail Address:

donna.velasquez@siemens.com

Date Prepared:

October 28th, 2014

2. Device Name

Proprietary Name:

IMMULITE® 2000 High Sensitivity CRP Calibration Verification Material

Measurand:

Quality Control materials for IMMULITE® 2000 High Sensitivity CRP assay

Type of Test:

Calibration Verification Material (CVM) for IMMULITE® 2000 High Sensitivity CRP assay

Regulation Section:

21 CFR 862.1660, Quality Control Material

Classification:

Class I Reserved

Products Code:

JJX – Single (Specified) Analyte Controls (Assayed and Unassayed)

Panel:

Clinical Chemistry (75)

3. Predicate Device Name

IMMULITE 2000 Homocysteine Calibration Verification Material (CVM)

Predicate 510(k) No:

K133128

4. Device Description:

The IMMULITE® 2000 High Sensitivity CRP Calibration Verification Material (CVM) contains one set of four vials, 2mL each. CVM1 contains a bovine protein/buffer with 0.098% sodium azide and preservative. CVM2, CVM3, and CVM4 contain various levels of human CRP in a bovine protein/buffer with 0.098% sodium azide and preservative.

- 5. Intended Use:**
Indication for Use: See Indications for Use Statement below
 The IMMULITE® 2000 High Sensitivity CRP Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE High Sensitivity CRP assay on the IMMULITE 2000 systems
- Special Conditions for Use Statement(s):**
Special Instrument Requirements: For prescription use only
 IMMULITE® 2000 Systems
- 6. Technological Characteristics and Substantial Equivalence Comparison with Predicate:**
 A comparison of the device features, intended use, and other information demonstrates that the IMMULITE® 2000 High Sensitivity CRP Calibration Verification Material (CVM) is substantially equivalent to the predicate device as summarized in **Table 1.**

Table 1: Substantial Equivalence Comparison

SIMILARITIES		
	Candidate Device IMMULITE 2000 High Sensitivity CRP CVM	Predicate Device IMMULITE 2000 Homocysteine CVM
Intended Use	The IMMULITE® 2000 High Sensitivity CRP Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE High Sensitivity CRP assay on the IMMULITE 2000 systems	The IMMULITE® 2000 Homocysteine Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Homocysteine assay on the IMMULITE 2000 systems
Form	Liquid	Same
Levels	4	Same
Stability	Stable unopened until the expiration date	Same
Matrix	Bovine protein/buffer matrix	Same
Use	Single Use Only	Same

DIFFERENCES		
	Candidate Device IMMULITE 2000 High Sensitivity CRP CVM	Predicate Device IMMULITE 2000 Homocysteine CVM
Storage	2-8°C	≤20°C
Analyte	High Sensitivity CRP	Homocysteine

7. Non-Clinical Performance Testing

Performance testing has been carried out to demonstrate that this device meets the performance specifications for its intended use. The following tests were performed on the candidate device.

Stability Summary:

The stability study was conducted to validate real-time shelf life and open component (in-use or open vial) claim for the IMMULITE 2000 High Sensitivity CRP Calibration Verification Material (CVM) to ensure that it maintains optimal product performance on IMMULITE 2000 platforms throughout the established shelf life of the CVM. The Calibration Verification Materials are stable up to 11 months when stored at 2-8°C prior to opening, and for 8 hours at ambient or room temperature (15-25°C) after opening.

Stability Protocol Summary:

The CVM study protocols are run as part of the calibrator stability testing. The stability CVMs and reference CVMs are run in duplicate (as a minimum) at the time points shown in **Table 2a-c** and the dose value determined from the reference calibrator curve.

Table 2a: Stability Protocol Summary – LCRPCVM Lot 025

CVM Level	Time-Points (Months)			
LCRPCVM1	Day 0	12	18	23
LCRPCVM2	Day 0	12	18	23
LCRPCVM3	Day 0	12	18	23
LCRPCVM4	Day 0	12	18	23

Table 2b: Stability Protocol Summary – LCRPCVM Lot 026

CVM Level	Time-Points (Months)			
LCRPCVM1	Day 0	7	8	12
LCRPCVM2	Day 0	7	8	12
LCRPCVM3	Day 0	7	8	12
LCRPCVM4	Day 0	7	8	12

Table 2c: Stability Protocol Summary – LCRPCVM Lot 090

CVM Level	Time-Points (Months)			
LCRPCVM1	Day 0	4	6	11
LCRPCVM2	Day 0	4	6	11
LCRPCVM3	Day 0	4	6	11
LCRPCVM4	Day 0	4	6	11

Stability Acceptance Criteria Summary:

The Acceptance Criteria for the IMMULITE 2000 High Sensitivity CRP Calibration Verification Material (CVM) are in 2 parts. Part 1 consists of guideline acceptance criteria which require dose value of stability CVMs to fall between $\pm 20\%$ of the assigned dose for CVM level 2, $\pm 6\%$ of the assigned dose for level 3 and $\pm 10\%$ of assigned dose for CVM level 4. Part 2 review limits criteria which require dose value of the controls to be within 2 Standard Deviations (SD) of the control target value when generated from the stability calibrator curve. If the result is not within acceptable dose

range of $\pm 20\%$ of the assigned dose for CVM level 2, $\pm 6\%$ of the assigned dose for level 3 and $\pm 10\%$ of assigned dose for CVM level 4 then additional data review is conducted using part 2 criteria.

Traceability:

The IMMULITE 2000 High Sensitivity CRP CVMs are traceable to WHO 1st IS 85/506 and CRM 470. The CVMs are manufactured using qualified materials and measurement procedures.

Value Assignment:

The IMMULITE 2000 High Sensitivity CRP CVMs are 4 level materials which are a subset of 10 level High Sensitivity CRP calibrators. Calibrators are not commercialized but are used internally during manufacture and release testing of High Sensitivity CRP reagents and two point adjustors. The IMMULITE calibrators and therefore CVMs are value assigned using assigned reference calibrators. The CVMs dose values are generated using curve generated by assigned reference calibrators. The CVM values are calculated based on the recovered values for each run on each instrument independently. The CVM values are then averaged across all systems. Quality control is performed by calculating the recovery of patient samples and controls using the assigned CVM values. The controls must fall within their target ranges. Three levels of commercially available controls and 28 samples (21 normal samples and 7 spiked samples) were used to validate calibrator/CVM value assignments.

Expected Values/Target Values/Reference Range:

The CVMs are manufactured using qualified materials and measurement procedures. The High Sensitivity CRP CVMs were tested on 15 replicates in total comprised of 5 runs and 3 replicates per run on 4 IMMULITE 2000 systems and 3 different reagent kit lots. The CVMs dose values are generated using curve generated by assigned reference calibrators. The CVM values are calculated based on the recovered values for each run on each instrument independently. The CVM values are then averaged across all systems. Quality control is performed by calculating the recovery of patient samples and controls using the assigned CVM values. The Guideline Range (95% confidence interval) for each CVM level was established based on the Target Mean and ± 2 Standard Deviation (SD). *

The expected assay range is 0.2 to 100 mg/L. The target values in **Table 3** can be considered as guidelines.

Table 3: Analyte Target Range Levels

Analyte target levels	CVM Level	**Target Mean (mg/L)	Standard Deviation (SD)	Guideline $\pm 2SD$ Range (mg/L)	
	LCRPCVM1	0.00	-	0.00	≤ 0.20
	LCRPCVM2	1.27	0.125	1.02	1.52
	LCRPCVM3	11.1	0.71	9.68	12.5
	LCRPCVM4* 65% LCRPCVM4 + 35% LCRPCVM1	157 102	- 7.575	- 86.9	- 117
Assay Range	0.2 to 100 mg/L				

Note* CVM4 requires dilution to ensure that the target value is within the +10% of the top of the reportable range of the assay.

** When CVMs are run by the customer, an actual value below and above the assay range will result when the customer programs the CVMs as calibration verifiers in the instrument software. If programmed as a patient or control, then the software will give values as < or > the assay lower and upper range.

Each laboratory should establish their limits for acceptability based on methodology, clinical significance and medical decision levels of the test analyte. The representative, total precision tabulated in the respective assay instructions for use may be considered as one factor when establishing local, acceptable ranges. The values provided above may be considered as guidelines. Value assignment is lot specific.

Standard/Guidance Documents Referenced:

- CEN 13640 Stability Testing of In Vitro Diagnostic Reagents
- Guidance for Industry – Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators
- Guidance for Industry and FDA Staff – Assayed and Unassayed Quality Control Material

Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10

8. Conclusion:

The IMMULITE® 2000 High Sensitivity CRP Calibration Verification Material is substantially equivalent to the predicate device intended for similar use. The substantial equivalence of the device is supported by the non-clinical testing and was found to be comparable and supports the claims of substantial equivalence, product safety and effectiveness. Based on the testing completed and the comparisons with predicate device, the IMMULITE® 2000 High Sensitivity CRP Calibration Verification Material does not raise any new questions on safety and effectiveness and the results support a determination of substantial equivalence.